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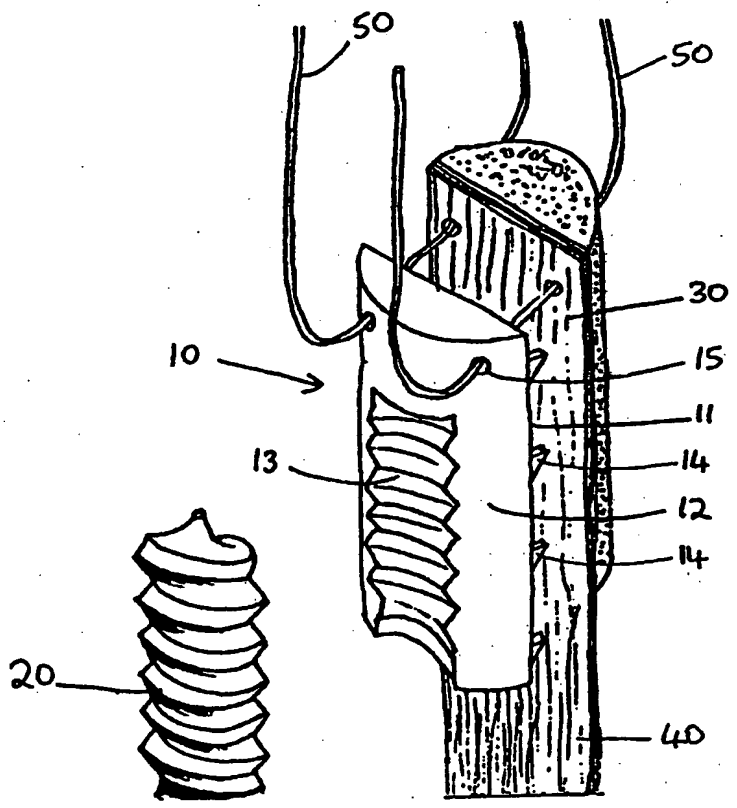
(54) Title: BONE IMPLANT

(57) Abstract

The invention relates to an insert (10) for use in combination with a bone graft, the insert (10) comprising a body having a bone graft–facing surface (11) and an opposing surface having a screw–engaging element (13) formed thereon; and means for securing the insert to the bone graft. Such an insert (10) can be used in anterior cruciate ligament reconstruction.



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BONE IMPLANT

This invention relates to a bone implant. In particular, it relates to an insert for use in combination with a bone graft especially in anterior cruciate ligament (ACL) reconstruction.

Injury to the ACL is one of the most common knee injuries sustained in athletics. Interarticular reconstruction using a bone-patellar tendon-bone autograft is the most commonly performed procedure. This procedure requires a stable method of fixation of the bone blocks within the tibial and femoral tunnels. One of the techniques used is interference screw fixation [see "The biomechanics of interference screw fixation of the patellar tendon of anterior cruciate ligament grafts", Brown C.H. et al., American Journal of Sports Medicine, Vol. 21, pages 880-886 (1993); and "The treatment of injuries of the anterior cruciate ligament", Johnson R.J. et al., Journal of Bone and Joint Surgery, Vol. 74a, pages 140-151 (1992)]. However, the interference screw fixation procedure has a number of disadvantages, including the following:

(1) Screw insertion may inadvertently advance the bone plug along the bone tunnel, affecting graft length and tension, unless constant tension is maintained on the graft using holding sutures during placement.

(2) The sutures themselves may be divided by the screw

threads, so that a holding suture must be placed on the side of the bone plug opposite screw threads.

(3) If the screw projects beyond the bone block, there is a risk of laceration or weakening of the tendinous portion of the graft, leading to graft failure.

(4) The screw threads may damage the tendon fibres during screw placement.

(5) The screw threads may divide the holding sutures on the bone block surface during insertion, losing tension on the graft.

(6) The screw may drive the bone block along the tunnel, again affecting the graft length and tension unless constant tension is kept on the holding sutures.

(7) The screw may diverge from the graft during placement, thereby weakening the interference.

(8) Although great care is usually taken to centre the femoral tunnel on the isometric point, the graft is displaced into an eccentric position in the tunnel by the interference screw and is no longer isometric.

(9) This loss of isometric position is exaggerated

further if, as is commonly done, the graft is placed in reverse in the tunnel to prevent the screw cutting the graft; the tendon fibres are now flush with the tunnel wall instead of centered in the tunnel.

(10) This practice also has the effect of leaving the cortical aspect of the bone block, covered with periostrum and the continuation of the quadriceps expansion/patellar tendon, adjacent to the tunnel wall. If the cut surface, i.e. the cancellous aspect of the block were left in contact with the tunnel wall, the incorporation of the graft would be optimised.

It is an object of the invention to avoid or minimise the drawbacks of the prior art.

According to the present invention there is provided an insert for use in combination with a bone graft, the insert comprising a body having a bone-graft-facing surface and an opposing surface having a screw-engaging element formed thereon; and means for securing the insert to the bone graft.

The invention also provides a bone graft assembly comprising a bone graft and an insert of the invention as described above attached thereto.

The insert preferably comprises a rigid solid body formed from any suitable material, examples of

which include metals, such as stainless steel and titanium; polymers such as poly-L-lactid acid; and bioceramic materials such as hydroxyapatite.

The insert is preferably substantially D-shaped in cross-section, the flat portion forming the bone-graft-facing surface and the curved portion having the screw-engaging element formed thereon.

The screw-engaging element preferably comprises a threaded recess extending at least along a portion of the insert body, for threaded engagement with an interference screw.

The insert body may be tapered along its length, the threaded recess extending from the narrower end thereof and/or the recess may be tapered, depending on the configuration of the screw to be engaged.

The means for securing the insert to the bone graft may comprise a plurality of projections of any suitable shape extending outwardly from the bone-graft-facing surface of the insert. The projections are conveniently about 2 mm in depth. They may be randomly arranged or have a defined arrangement. A suitable arrangement may comprise eight spaced apart projections, each presenting a substantially triangular external configuration, arranged in two rows of four.

The projections are preferably integral with the insert body.

The securing means may also comprise one or more recesses formed in the bone-graft-facing surface of the insert.

The insert preferably additionally includes a plurality of apertures therethrough for receiving holding sutures, to supplement the fixation achieved by the securing means.

An embodiment of the invention will now be described by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of an insert according to the invention with a bone block and interference screw;

Figure 2 is a rear plan view of the insert of Figure 1;

Figure 3 is a longitudinal section through the femoral bone tunnel as the bone block and insert of Figure 1 are inserted therein; and

Figure 4 is a longitudinal section through the femoral bone tunnel with the insert, bone block and interference screw of Figure 1 *in situ*.

Referring now to the drawings in which like numerals indicate like parts, there is shown an insert 10 according to the invention. The insert 10 has a

rigid, solid, elongate body which is adapted to be interposed in use between an interference screw 20 and a bone graft in the form of a block 30. The bone block 30 is shaped to fit the bone tunnel into which it is to be inserted. The bone block 30 includes patellar tendon 40. The present embodiment is described in relation to anterior cruciate ligament (ACL) reconstruction.

The insert 10 has a substantially flat bone block-facing surface 11 and an opposing curved surface 12. The surface 12 includes a threaded recess 13 extending along a portion thereof for threaded engagement with the interference screw 20.

Projections 14 in the form of spikes of substantially triangular external configuration extend outwardly from the substantially flat surface 11. There are conveniently eight projections 14 spaced apart and arranged in two rows of four. The projections 14 are preferably integral with the insert 10 and are suitably about 2 mm in depth.

The insert 10 and bone block 30 should be coterminous. The insert 10 is conveniently about 25 mm in length. In such an insert 10, the threaded recess 13 is approximately 21 mm in length. The threaded recess 13 is formed such that it may be engaged by a 7 x 20 mm interference screw.

In use, the flat surface 11 is applied directly

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to the outer (periosteal) surface of the bone block 30 prior to graft insertion. Fixation of the insert 10 to the bone block 30 is achieved by the projections 14 which penetrate the soft-tissue covering into the periosteum of the bone block 30. Fixation can also be supplemented by the passing of holding sutures 50 of the bone block 30 through apertures 15 in the insert 10 before attaching them to the passing guide wire (not shown) and drawing the insert 10 and bone block 30 as a unit into the bone tunnel, i.e. the femoral tunnel 60 or the tibial tunnel (not shown).

As the interference screw 20 is introduced between the bone tunnel wall and the insert 10, it produces increasing compression of the insert-bone block (10,30) unit against the opposite wall of the bone tunnel.

Some advantages of the insert according to the invention are as follows:

1. It permits placement of the graft in the bone tunnel with the cancellous bone aspect of the bone block orientated towards the tunnel wall, resulting in a qualitative improvement in the degree of graft incorporation.

2. It permits, as a result of this position, retention of the patellar tendon-bone block interface at a more central point in the bone tunnel, thereby better retaining the isometricity of the graft.

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3. It avoids contact between the graft and the screw during insertion.

4. It engages or captures the screw during its insertion, reducing any tendency for graft-screw divergence.

5. It achieves a comparable or greater level of fixation strength to that provided by the interference screw alone.

The invention is not limited to the embodiment described herein, which may be modified or varied without departing from the scope of the invention.

CLAIMS:

1. An insert for use in combination with a bone graft, the insert comprising a body having a bone graft-facing surface and an opposing surface having a screw-engaging element formed thereon; and means for securing the insert to the bone graft.

2. An insert according to claim 1 comprising a rigid solid body formed from a metal such as stainless steel or titanium; or a polymer such as poly-L-lactid acid; or a bioceramic material such as hydroxyapatite.

3. An insert according to claim 1 or 2 which is substantially D-shaped in cross-section, the flat portion forming the bone-graft-facing surface and the curved portion having the screw-engaging element formed thereon.

4. An insert according to any of claims 1 to 3, wherein the screw-engaging element comprises a threaded recess extending at least along a portion of the insert body, for threaded engagement with an interference screw.

5. An insert according to any of claims 1 to 4, wherein the body is tapered along its length, the threaded recess extending from the narrower end thereof and/or the recess is tapered.

6. An insert according to any of claims 1 to 5, wherein the means for securing the insert to the bone graft comprises a plurality of projections extending

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outwardly from the bone graft-facing surface of the insert.

7. An insert according to claim 6, wherein the projections are randomly arranged and/or are integral with the insert body.

8. An insert according to any of claims 1 to 7, wherein the securing means additionally comprises one or more recesses formed in the bone graft-facing surface of the insert.

9. An insert according to any of claims 1 to 8 which additionally includes a plurality of apertures therethrough for receiving holding sutures.

10. A bone graft assembly comprising a bone graft and an insert according to any of claims 1 to 9 attached thereto.

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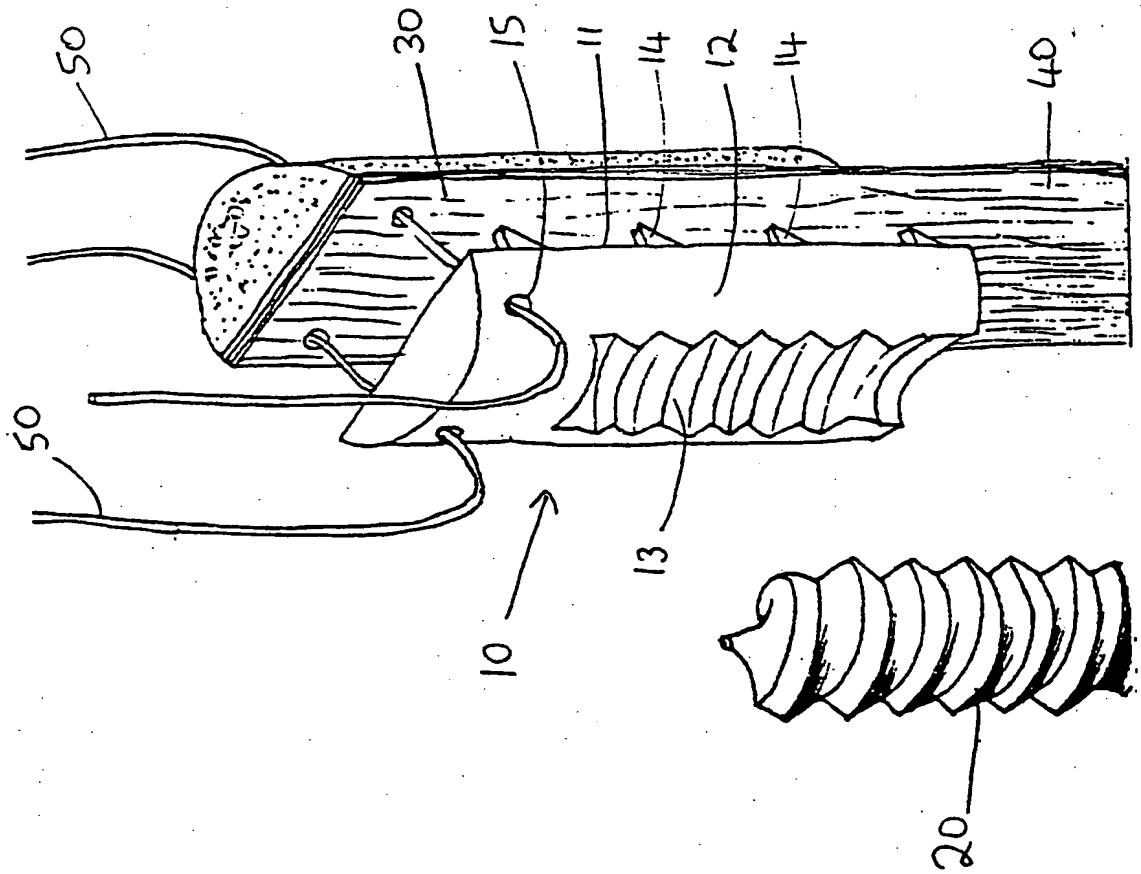

FIG. 1

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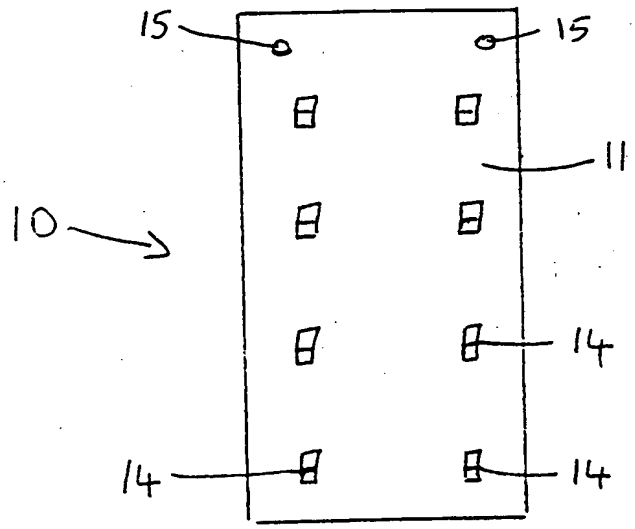

FIG. 2

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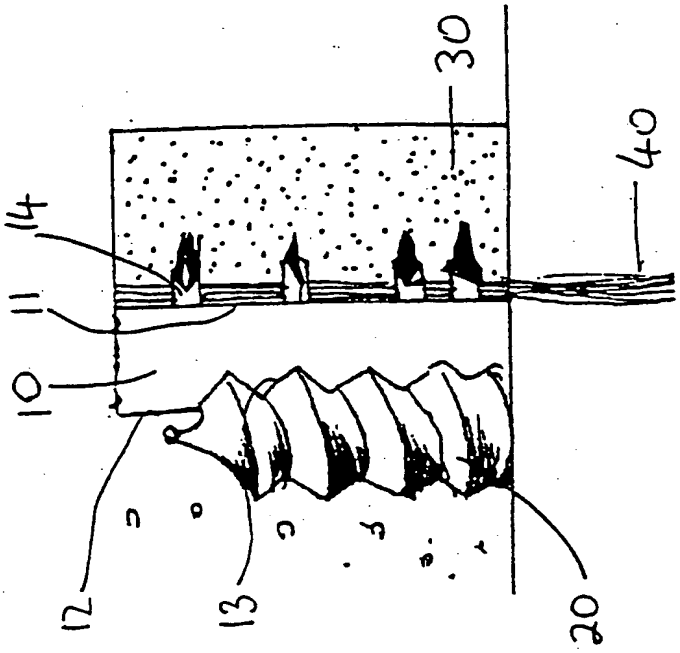

FIG. 4

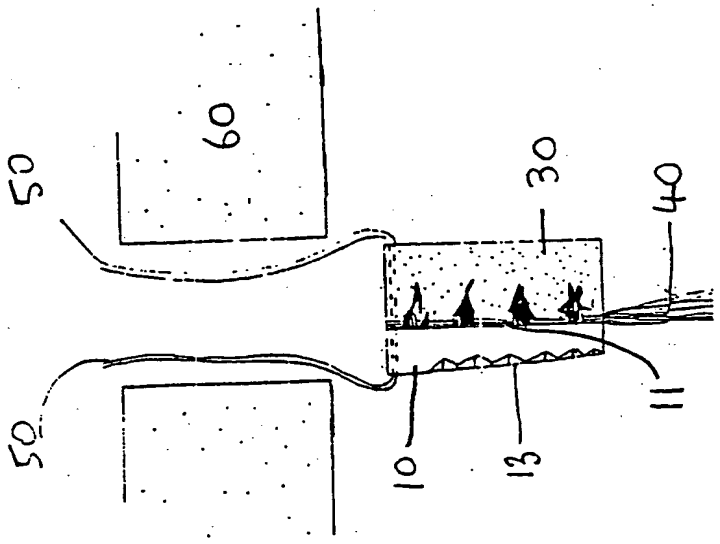

FIG. 3

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INTERNATIONAL SEARCH REPORT

Int ional Application No
PCT/IE 97/00077

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	EP 0 596 829 A (SULZER MEDIZINALTECHNIK AG) 11 May 1994 see figures	1,2,10
A	WO 94 28799 A (MITEK SURGICAL PROD) 22 December 1994 see figures 5-9	1,2,6,7, 9,10
A	EP 0 425 140 A (PFIZER HOSPITAL PROD) 2 May 1991 see figures	1,2,6-8, 10

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[X] Further documents are listed in the continuation of box C.

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